JAN 3 1 2012

510(k) SUMMARY

Medical Compression Systems (DBN) Ltd.'s ActiveCare DVT and ActiveCare+SFT Systems

Submitter's Name, Address, and Telephone Number

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Date Prepared: January 24, 2012

Name of Device and Name/Address of Sponsor

ActiveCare DVT and ActiveCare+SFT Systems

Classification Name and Information

Compressible Limb Sleeve
Class II; Product Code: JOW
Regulation No. 870.5800
Panel: Cardiovascular Devices

Predicate Devices

Medical Compression Systems (DBN) Ltd. ActiveCare DVT (K023573)
Medical Compression Systems (DBN) Ltd. ActiveCare+SFT (K060146)

Purpose of 510(k) Notice

This 510(k) was submitted in order to clear minor modifications to the ActiveCare DVT System and the ActiveCare+SFT System. Specifically, the following modifications were made to the cleared systems: addition of an OVP circuit, exterior device color change, addition of secondary source hardware components, minor software updates, and minor user manual clarifications.

Intended Use / Indications for Use

The ActiveCare DVT and ActiveCare+SFT Systems are prescription devices that induce Continuous Enhanced Circulation Therapy of the lower limbs.

The Systems are intended for use in:

- Preventing Deep Vein Thrombosis (DVT).
- Enhancing blood circulation.
- Diminishing post-operative pain and swelling.
- Reducing wound-healing time.
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers.
- Treatment of chronic venous insufficiency.
- Reducing edema.

Technological Characteristics / Principles of Operation

The ActiveCare DVT and ActiveCare+SFT Systems are prescription, pneumatic compression Systems designed to apply sequential compression to the lower limb. The control units of the ActiveCare DVT and ActiveCare+SFT Systems provide the user with several treatment options: compression of the foot – single or double, compression of the calf – single or double, compression of the thigh – single or double, and combined compression of any combination of two sleeves. The foot compression program is an intermittent pressure pulse application to a single celled foot sleeve. The calf and thigh compression program is a sequential intermittent application of a pressure to a three-celled cuff sleeve.

Performance Data

A series of performance testing, including risk analysis, electrical safety, software validation and field testing were performed to demonstrate that the modified ActiveCare DVT and ActiveCare+SFT Systems with the described modifications do not raise any new questions of safety and efficacy. Based on these tests results, Medical Compression Systems (DBN) Ltd. believes that the modified ActiveCare DVT and ActiveCare+SFT Systems are substantially equivalent to the cleared ActiveCare DVT and ActiveCare+SFT Systems without raising new safety and/or effectiveness issues.

Substantial Equivalence

The ActiveCare DVT and ActiveCare+SFT Systems are substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available Medical Compression Systems (DBN) Ltd.'s ActiveCare DVT and ActiveCare+SFT Systems, previously cleared under K023573 and K060146, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 3 1 2012

Medical Compression Systems (DBN), LTD
c/o Mr. Jonathan S. Kahan
Hogan Lovells US LLP
Columbia Square
555 13th Street, NW
Washington, DC 20004

Re: K113525
Trade/Device Name: ActiveCare DVT and ActiveCare+SFT Systems
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeves
Regulatory Class: Class II
Product Code: JOW
Dated: November 29, 2011
Received: November 29, 2011

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113525

Indications for Use Statement

510(k) Number (if known): K113525

Device Name: ActiveCare DVT and ActiveCare+SFT Systems

Indications for Use:

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- Treatment of chronic venous insufficiency.
- Reducing edema.

Prescription Use __X__ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113525